REMARKS

In response to the Office Action mailed March 14, 2008, Applicants have amended claim 4. No claims have been canceled and no new claims have been added. It is urged that support for all the above amendments may be found throughout the specification as originally filed. No new matter has been added. The above amendments are not to be construed as acquiescence with regard to the Examiner's rejections and are made without prejudice to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application. Following the amendments, claims 4-6 are currently under examination in the application. Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks.

Claim Rejections Under 35 U.S.C. §103(a)

Claims 4-6 stand rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over Burton *et al.* (U.S. Patent No. 5,217,962). Specifically, the Examiner alleges that Burton *et al.* disclose the N-acetyl glucosamine (NAG) is useful for treating symptoms such as inflammation and such local lesions as psoriasis. The Examiner concludes the skilled artisan would find it obvious to treat inflammation and lesions caused by any disease or condition, including viral infections.

Applicants respectfully traverse this basis for rejection and submit that Burton *et al.* fail to establish a *prima facie* case of obviousness against the presently claimed invention, because they do not teach or suggest every limitation of the instant claims. Moreover, one having ordinary skill in the art would not find it obvious to arrive at the presently claimed invention in view of Burton *et al.*

Applicants, without acquiescence and solely to clarify a particular aspect of the presently claimed invention, have amended claim 4 to recite:

> "A method to control the micro-heterology variation in a patient~~for controlling local lesions and systematic symptoms caused by viral infections~~, wherein a pharmaceutical composition comprising an effective amount of N-acetyl-D-glucosamine or pharmaceutically acceptable salts thereof is administered to ~~a~~ the patient, thereby controlling local lesions

and systematic symptoms caused by viral infections in the patient ~~to control the micro-heterology variation in the patient.~~"

Support for this amendment may be found throughout the specification as filed, as thus, does not constitute new matter.

The Examiner contends that the skilled artisan would find it obvious to treat any disease or condition, including viral infections by administering NAG to a patient. Applicants respectfully disagree and submit that Burton *et al.* merely teach or suggest that administering NAG to a patient will alleviate symptoms resulting from deficiencies in the synthetic pathways involving NAG or glycosaminoglycans (GAG).

For example, Burton *et al.* teach that "the novel feature of their invention is the use of an external source of NAG which is ingested to rectify a deficit which, while not necessarily affecting the basic cause of the disorder of psoriasis, can provide for the formation of essential tissue components whose deficiency is a major facet of the disease" (col. 2, lines 53-58). In further evidence of their hypothesis, Burton *et al.* teach that "A major component of the material which covers the cells and occupies the spaces between them is GAG, which are by weight approximately half composed of amino sugars derived from NAG" (col 1. lines 25-29).

Burton *et al.* also teach that NAG is effective in patients suffering from inflammatory bowel disease (IBD). Burton *et al.* submit that the mucosal tissue structure is rich in amino sugars derived from NAG and that the availability of NAG is critical to synthesis of said structure. Burton *et al.* teach that NAG incorporation in the intestinal mucosa is three times greater in IBD patients than in patients without IBD (col. 4, lines 52-55). As evidence, Burton *et al.* submit that proglumide (e.g., a therapeutic agent), which protects against ulcer formation has been shown to stimulate the incorporation of NAG into mucosal glycocalyx and is considered the reason for its effectiveness. Burton *et al.* conclude that NAG is useful in many situations where the synthetic processes are less than adequate to meet the physiological demand (col. 5, lines 41-44).

However, nowhere do Burton *et al.* event remotely suggest that that NAG could be used to control micro-heterology in a patient suffering from a viral infection. Furthermore, the Examiner has not provided any example of a viral deficiency that results in an NAG deficiency. One having ordinary skill in the art would recognize that Burton *et al.* only disclose

or suggest that administering NAG to a patient suffering from a disorder that results in an NAG deficiency will alleviate symptoms resulting from said NAG deficiency. Thus, Applicants submit that the skilled artisan would not find it obvious to control the micro-heterology variation in a patient and thereby control local lesions and systematic symptoms caused by viral infections in the patient.

In contrast, Applicants teach that the effect of administering N-acetyl-D-glucosamine or pharmaceutically acceptable salts thereof is not to control the infection of virus per se, but to control the micro-heterology variation in a patient, thereby controlling local lesions and the systematic symptoms caused by viral infections. For instance, in Example 3 of the as-filed specification, Applicants demonstrate that only cells cultured in the presence of NAG, and not control cells, can regulate the cell micro-heterology variation in order to adapt to the continuously changing cell-culture environment, which results in continuous cell proliferation. Example 4 of the as-filed specification teaches that in rats inoculated with B16 tumor cells, NAG controlled the micro-heterological variation and further protected the NAG treated rats from acquiring tumors. In another word, after the administration of N-acetyl-glucosamine, the living body can be stabilized in normal activity of cells and molecules as usual, therefore, the normal activities of the components in the living body are maintained, so local or systematic lesions will not occur."

Accordingly, Burton *et al.* fail to teach a method wherein the administration of NAG is used to control the micro-heterology in a patient to thereby control local lesions and the systematic symptoms caused by viral infections. Thus, one having ordinary skill in the art would not find it obvious to arrive at the presently claimed invention in view of Burton *et al.*, and thus, the Examiner has failed to establish a *prima facie* case of obviousness against the presently claimed invention.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

All of the claims remaining in the application are now believed to be allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC

/William T. Christiansen/
William T. Christiansen, Ph.D.
Registration No. 44,614

WTC:jto

701 Fifth Avenue, Suite 5400
Seattle, Washington 98104
Phone: (206) 622-4900
Fax: (206) 682-6031

1025219_1.DOC